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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,776	12/22/2000	Hans-Ulrich Demuth	20784/4	7886

21710 7590 02/25/2003

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EXAMINER

CHISM, BILLY D

ART UNIT PAPER NUMBER

1654

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/745,776

Applicant(s)

DEMUTH ET AL.

Examiner

B. Dell Chism

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 6 and 8-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 7 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION**

This Office Action is in response to Paper No. 13, filed 11 December 2002, wherein Applicants elected Group I, claims 1-7 and 13, and prodrug compound Pro-Ile-Thia, with traverse. The Applicants argue that the restriction is not required because the searches for Group I would include, if not cover completely, the art for Group II. As the Examiner stated in the previous Office Action, filed 19 September 2002, the searches for the different groups might include similar/same art, however, the searches would not be inclusive of each other. Thus, additional searches would be required and burdensome on the Examiner. Applicants' traversal is unpersuasive and the action is made FINAL. Furthermore, under the 35 USC §121 language of the previous Office Action, the Applicants were further restricted to one invention of a prodrug compound and this restriction under 35 USC §121 was also traversed by the Applicants. Again, for the reasons stated above, the search for invention would not be inclusive of all other inventions and therefor this restriction requirement is made FINAL. Consequently, the elected prodrug compound Pro-Ile-Thia was free of the prior art, thus, the Examiner searched for additional species. The results of those searches are discussed in the following rejection(s).

Claims 1-13 are pending. Claims 8-12 are withdrawn from consideration as being drawn to the nonelected subject matter of Group II. Claims 2-4 and 6 are withdrawn from consideration as being drawn to nonelected subject matter. Claims 1, 5, 7 and 13 are under consideration by the Examiner.

***Abstract***

The abstract of the disclosure is objected to because the abstract contains more than one paragraph. Correction is required. See MPEP § 608.01(b).

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 5, 7 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected for the indefinite use of the phrase "Prodrug compounds." The Applicants should amend the claim to read in the singular form, i.e. A prodrug compound.

Claim 1 is rejected for being drawn to non-elected subject matter.

Claims 5, 7 and 13 are rejected for the recitation of plural "compounds" regarding the claimed product. Claim 7 should read on the singular form of "A prodrug compound" and claims 5 and 13 should read as "the compound of claim 1"

Claim 7 is rejected for the recitation of the indefinite terms "optionally" and "customary". The terms "optionally" and "customary" render the claim indefinite because the specification fails to teach the metes and bounds of what is encompassed. Regarding the term "optionally", if an ingredient, a step, or other structural element is truly optional, i.e. its presence is not necessary for attainment of the result that is the object of the invention, then the recitation thereof does not belong in the claim. Regarding the term "customary", absent some disclosure in the specification of what is encompassed within its meaning, the metes and bounds of the claimed invention cannot be ascertained and the claim is indefinite".

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Claim 13 is rejected for the recitation of the indefinite term "preventing", wherein if the Applicants were to amend claim 13 to read, "inhibiting the degradation" then claim 13 would be within the concise scope of the claimed invention regarding this rejection. Claim 13 is also rejected for the use of the term "complex" wherein if the Applicants were to delete "complex" and use the term "composition" then claim 13 would be clearer regarding the claimed invention.

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanaka *et al.* 1997 (Int. J. Immunopharmac., Vol. 19, No 1, pp. 15-24, see abstract, pp. 18-19). Tanaka *et al.* teaches a DP IV inhibitor of general formula A-B-C, wherein A is an amino acid, B is a bond between A and C, and C is a stable inhibitor of DP IV (i.e., thiazolidide). "Oral administration" is an intended use and not considered a limitation of claim 7.

3. Claims 1 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Augustyns *et al.* 1997 (Eur J Med Chem, Vol. 32, pp. 301-309, see abstract). Augustyns *et al.* teaches DP IV inhibitor compound consisting the A-B-C formula of claim 1 (i.e., 1-(L-Isolucyl)-3(S)-fluoropyrrolidine). "Oral administration" is an intended use and not considered a limitation of claim 7.

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***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Augustyns *et al.* 1997 (Eur J Med Chem, Vol. 32, pp. 301-309, see abstract). Augustyns *et al.* teaches DP IV inhibitor compound consisting the A-B-C formula of claim 1 (i.e., 1-(L-Isolucyl)-3(S)-fluoropyrrolidine). Augustyns *et al.* does not teach a salt form. However, it has long been the practice in the chemical and pharmaceutical arts to produce compounds in the form of crystals to secure a pure product. There is no patentable distinction in the concept of a chemical compound in crystalline or salt form over the same compound in its amorphous form. In re Weijlard, 69 U.S.P.Q. 86, 87 (C.C.P.A. 1946). Further, changing the form, purity or other characteristic of an old product does not render the novel form patentable where the difference in form, purity or characteristic was inherent in or rendered obvious by the prior art. In re Cofer, 148 U.S.P.Q. 268 (CCPA 1966). Therefore, absent a showing of unobvious and superior properties, the instant claimed crystalline forms of known compounds would have been suggested to one skilled in the art. Additionally, since Applicant(s) are claiming a similar method of using the crystalline forms to that of the amorphous form, a showing of unobvious and superior properties in using the crystalline form for this similar method of use would also have to be shown.

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One skilled in the art would have been motivated to prepare different crystalline forms of known pharmaceutically useful compounds with the expectation of obtaining a pharmaceutically useful benefit, such as longer shelf life, stability, enhanced deliverability, etc. Therefore, absent a showing of unobvious and superior properties, the instant claimed crystalline forms of known compounds would have been suggested to one skilled in the art.

The compounds are of the same identical formula and as such would be expected to have the same utility. The difference, if any, may reside in there being different crystalline forms. One of ordinary skill in the art would be motivated to prepare a different crystalline form of a known organic pharmaceutically active compound in the expectation of obtaining that very compound but with enhanced properties, e.g. improved solubility, shelf-life, improved mode of administering properties, etc. In the absence of a showing of a viable unexpected property (not just a difference in X-ray crystallography), the instant claimed invention is found obvious.

#### *Art of Record*

Chemical Abstracts, vol. 115. No. 15, 14 October 1991, Columbus, Ohio, US; abstract no. 149947q, SCHOEN EKKEHARD *et al.*: "dipeptidyl peptidase IV in the immune system. Effects of specific enzyme inhibitors on activity of dipeptidyl peptidase IV and proliferation of human lymphocytes." Seite 37; XP002114197 Zusammenfassung & BIOL. CHEM. HOPPE-SEYLER, Bd. 372, Nr. 5, 1991, Seiten 305-311.

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*Conclusions*

No claims allowed.

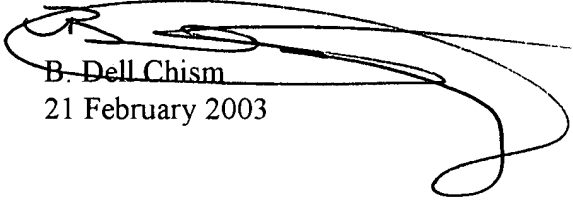
Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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B. Dell Chism  
21 February 2003



  
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